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HAUGEN AND NIKOLAI
820 INTERNATIONAL CENTRE
900 SECOND AVENUE SOUTH
MINNEAPOLIS MN 55402-3325

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

☒ This application has been examined ☒ Responsive to communication filed on 3-31-95 ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~30~~ days from the date of this letter.
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

1. ☒ Notice of References Cited by Examiner, PTO-892.
2. ☐ Notice of Draftsman's Patent Drawing Review, PTO-948.
3. ☐ Notice of Art Cited by Applicant, PTO-1449.
4. ☐ Notice of Informal Patent Application, PTO-152.
5. ☐ Information on How to Effect Drawing Changes, PTO-1474.
6. ☐ _____.

Part II SUMMARY OF ACTION

1. ☒ Claims 59-79 are pending in the application.

Of the above, claims _____ are withdrawn from consideration.

2. ☒ Claims 42-58 have been cancelled.
3. ☐ Claims _____ are allowed.
4. ☒ Claims 59-79 are rejected.
5. ☐ _____ are objected to.
6. ☐ Claims _____ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. ... ...ation purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on _____. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable; ☐ not acceptable (see explanation or Notice of Draftsman's Patent Drawing Review, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on _____. has (have) been ☐ approved by the examiner; ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed _____, has been ☐ approved; ☐ disapproved (see explanation).
12. ☐ Acknowledgement is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☐ been received ☐ not been received ☐ been filed in parent application, serial no. _____; filed on _____.
13. ☐ Since this application apppears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

1) Claims 59-79 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 59, what is the relationship between the inner layer on line 4 of claim 59 and the inner layer on line 7 of claim 59? It is suggested to change "inner layer" on line 4 of claim 59 to --inner bonding layer-- and to change "an inner bonding layer consisting" on line 7 of claim 59 to --the inner bonding layer consists--.

In claim 59 line 8, there is no antecedent basis for "the outer tensile layer". In claim 59 line 16 there is no antecedent basis for "the tensile layer". It is suggested to delete --tensile-- on line 8 of claim 59 and to change "tensile" on line 16 to --outer--.

In claim 59 line 11 there is no antecedent basis for "said parison". It is suggested to insert --to form a parison-- after "inner layer" on line 4 of claim 59.

In claim 59 steps (d) and (e), there is no clear antecedent basis for "the expander member" and "the expander" respectively. It is suggested to change "to establish inflated dimensions" on line 14 of claim 59 to --to form an expander member-- and to insert --member-- after "expander" on line 19 of claim 59.

Claim 59 is indefinite because it is unclear what additional separate "step" is being claimed in "step (d)". It is suggested to condense "steps" (b), (c), and (d) into one step.

In claim 62 line 4, which members of the group can be combined to form the "combinations thereof" (In other words, the recitation of "and combinations thereof" in the middle of the group is ambiguous). In claim 62 three lines from bottom should "the class" be --the group--?

Claims 65 and 71 are indefinite for the same reasons given for claim 59. Furthermore, the recitation of "melt bonding of said inner layer" in claim 65 is ambiguous. Furthermore, "flow molding fixture" in claim 71 should be --blow molding fixture--.

Claims 68 and 77 are indefinite for the same reasons given for claim 62.

In claim 73, the recitation of "melt bonding of said inner layer" in claim 65 is ambiguous.

In claim 75 line 1 should --and-- be deleted after "claim 71"?

2) The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as the specification as originally filed doe snot provide support for the invention as is now claimed.

Although the specification supports forming a biaxially oriented outer layer, the original specification fails to support the limitation of biaxially orienting the tensile layer and the inner bonding layer as set forth in claims 60 and 65-79. For example, where does the original specification support melting a biaxially oriented inner layer so as to bond the balloon to the catheter? Another example, where is the support for biaxially orienting a ethylene propylene inner layer or a polysiloxane inner layer as set forth in claim 66?

3) Claims 60 and 65-79 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

4) The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention

were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

5) Claims 59-69 are rejected under 35 U.S.C. § 103 as being unpatentable over Wang et al in view of Levy taken alone or further in view of Dyke and Parker[1].

Wang et al, directed to the catheter art, discloses coextruding a tube wherein the coextruded tube has an outer layer and an inner layer and forming the tube into a balloon such that the outer layer is biaxially oriented and the inner layer can be heat bonded to a catheter. The outer layer may be made from polyethylene terephthalate and the inner layer may be made from polyethylene. At columns 5 and 6, Wang et al discloses heating the tube, drawing it and expanding it, but does not specifically disclose heating and drawing the balloon so that it exhibits a burst strength greater than seven atmospheres.

Levy, also directed to the catheter art, teaches heating a polyethylene terephthalate tube, drawing the tube and radially

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[1]Wang et al (US Patent 5,195,969 filed 4-26-91) is prior art under 35 USC 102(e) since none of the claims in this application are fully supported by the disclosure of the 07/411,649 (none of the claims in this application are entitled to the benefit of the filing date of 07/411,649). See MPEP 201.11. For example, claim 59 is not fully supported by 07/411,649 since 07/411,649 fails to support the step of adhesively bonding using an adhesive. Another example: claim 68 is not fully supported by 07/411,649 since 07/411,649 fails to support using PEEK as the outer layer. Another example: claim 71 is not fully supported by 07/411,649 since 07/411,649 fails to support the limitation of the inner bonding layer as set forth on lines 9-13 of claim 71.

expanding the tube to form a biaxially oriented balloon having a burst pressure of at least 200 psi (13.6 atm).

As to claims 59 and 65, it would have been obvious to heat the coextruded tube of Wang et al, draw the coextruded tube and radially expand the coextruded tube so that the outer layer is biaxially oriented and the balloon has a burst pressure of at least 200 psi (13.6 atm) since (a) Wang et al and Levy both disclose forming a balloon for a catheter from a tube and (b) Levy suggests that a biaxially oriented balloon, which was made by heating a tube, drawing the tube and radially expanding the tube and which has a burst pressure of at least 200 psi (13.6 atm), is especially useful in medical dilation procedures. The limitation of expanding in a blow molding fixture would have been obvious in view of Levy's teaching to expand in the apparatus as shown in figure 1.

The limitation of biaxially orienting both layers as set forth in claims 60 and 65 would have been obvious in view of Wang et als' teaching to form a balloon from a tubular extrusion of at least two layers and Levy's teaching to biaxially orient a tubular extrusion. The limitation of bonding as set forth in claim 59 and 65 would have been obvious in view of Wang et al's teaching to melt the inner layer of the balloon to heat bond the balloon to a catheter tube. It appears that claim 59 does not require the use of a separate adhesive since claim 59 broadly

recites "using an adhesive". IN ANY EVENT: it would have been obvious to adhere the balloon with a separate adhesive since Dyke teaches bonding a balloon having two layers to a catheter by melting the inner layer of the balloon or by using an adhesive (col. 4 lines 45-47) and Parker teaches that coextruded layers may be adhered to a substrate with or without an adhesive. The limitation of the relative melting points of the two layers as set forth in claim 65 would have been obvious in view of Wang et al's teaching to melt the inner layer of the balloon, instead of the outer layer, to heat bond the balloon to a catheter tube. The limitation of the material of the outer layer as set forth in claims 62-64 and 67-70 would have been obvious in view of Wang et al's teaching that the material of the outer layer may be a polymer such as polyethylene terephthalate. The limitation of the bonding material as set forth in claims 61, 62, 66 and 68 would have been obvious in view of Wang et al's teaching to make the inner layer out of polyethylene.

6) Claims 71-78 are rejected under 35 U.S.C. § 103 as being unpatentable over Wang et al in view of Levy taken alone or further in view of Dyke and Parker as applied above and further in view of Merrill and Lambert.

Wang et al does not specifically recite coating the outer layer with a hydrophilic lubricous plastic.

Merrill teaches coating a balloon catheter with a hydrophilic material such as N-pyrrolidone.

Lambert teaches coating a catheter with a hydrophilic material such as polyvinylpyrrolidone. Lambert teaches that the hydrophilic coating has a much lower coefficient of friction when wet. Lambert teaches providing the hydrophilic coating on polymeric substrates such as polyesters.

As to claim 71, it would have been obvious to coat the outer layer with a hydrophilic lubricous plastic so that advantageously the outer polymeric surface of the balloon catheter will have a low coefficient of friction when wet since (a) Wang et al teaches bonding the balloon which comprises the outer layer to a catheter tube to form a catheter and (b) Merrill and Lambert suggest coating a catheter with a hydrophilic plastic coating, which one of ordinary skill in the art would readily recognize becomes slippery when wet.

The limitation of claim 74 would have been obvious in view of Merrill teaching to use N-vinyl pyrrolidone as a hydrophilic material. The limitations of claims 75-79 would have been obvious for the reasons given above with respect to claims 66-70. As to claim 72, note the examiner's comments regarding the bonding step in claim 59. As to claim 73, note the examiner's comments regarding claim 65.

7) Claims 59-70 are rejected under 35 U.S.C. § 103 as being unpatentable over Levy in view of Dyke, "Coextruded composite film" by Parker and Japan '353 (JA 53-45353) taken alone or further in view of Japan '463 (JA 58-188463).

Levy, directed to a balloon for a catheter, discloses extruding a tube of polyethylene terephthalate, heating the tube and drawing the tube and inflating the tube to form a biaxially oriented balloon having a burst pressure of at least 200 psi (13.6 atm). At col 4 lines 45-50, Levy discloses fabricating the balloon catheter comprising the balloon by means of conventional techniques.

Dyke, directed to a balloon catheter, teaches forming a balloon with integral thermoplastic bands and sealing the balloon to a catheter tube by fusing the thermoplastic bands with heat.

Parker, directed to coextruded composite film, teaches bringing a first layer and second layer of polymers into contact in a single die while they are still in a molten state, extruding the layers from the die to form a tube and inflating the tube with air to stretch the tube to a desired thickness. Parker teaches bonding takes place inside the extruder die head and the film leaves the die as a completely multilayered structure. Parker et al teaches that by providing the second layer a "good sealing film" having the all the desired properties of the first layer can be obtained. Parker specifically discloses: "All

coextruded films offer freedom from pinholes; it is virtually impossible for a pinhole in one film layer to line up with a pinhole which exits in another film." Parker lists "[a]dhesion to other substrates with or without adhesives" as being one of the "property advantages offered by specially tailored coextruded composite films"

Japan '353, directed to a stretched double layer film teaches melting two different resins, extruding them to form a laminated tube and then inflating the tube to stretch it to form a biaxially oriented double layer tube having good heat sealablity.

Japan '463 shows a balloon secured at each end to a catheter tube wherein the balloon comprises two layers 13 and 14. See abstract, figures. During an oral translation of Japan '463 by a PTO translator, the following information was obtained: Japan '463 discloses that layer 14 is a gas penetration layer which was formed by coating over a soft plastic film 13.

As to claim 59, it would have been obvious to coextrude the plastic material described by Levy with heat sealable plastic material to form a double layer tube before the steps of heating the tube, drawing the tube and radially expanding the tube to form the balloon and to use that double layer tube in the process of Levy since:

(a) Levy teaches forming a balloon from a polymeric tube and fabricating a catheter comprising the balloon using a conventional technique,

(b) Dyke suggests providing a double layer balloon having an outer layer and an inner heat sealable layer (two bands) so that a catheter comprising the balloon can be fabricated by sealing the balloon to a catheter tube with heat,

(c) Parker suggests coextruding a low melting point plastic material with a high melting point plastic material in order to form a double layer tube which has good sealing properties and is virtually free from pinholes and Japan '353 teaches extruding two different plastic materials to form a double layer tube and inflating the tube to form a biaxially oriented tube having "good heat sealablity and flexibility"

and optionally since:

(d) Japan '463 teaches forming a double layer balloon for the advantage of making the balloon more gas impermeable.

The limitation of expanding in a blow molding fixture would have been obvious in view of Levy's teaching to expand in the apparatus as shown in figure 1. Hence, Levy recognizes that the balloon must be attached to a catheter, Dyke suggests attaching a balloon to a catheter by bonding the balloon to the catheter with a sealable layer and the remaining secondary references teach that is well known/conventional in the bonding art to coextrude

two layers in order to provide a sealable layer. Advantages given by Parker for coextruding include adhesion to other substrates with or without adhesives and freedom from pinholes. These advantages are relevant to a catheter balloon since as noted above Dyke suggests adhering a balloon to a catheter and Levy teaches that a balloon is to be inflated. It is also noted that Levy and Japan '353 are directed to forming oriented tubes and that Dyke and Japan '353 are directed to providing a sealable layer on a tubular member.

The limitation of bonding as set forth in claims 59 and 65 would have been obvious in view of Dyke's teaching to heat the inner layer (heat sealable bands) of the balloon to fuse the balloon to a catheter tube. It appears that claim 59 does not require the use of a separate adhesive since claim 59 broadly recites "using an adhesive". IN ANY EVENT: it would have been obvious to adhere the balloon with a separate adhesive since Dyke teaches bonding a balloon having two layers to a catheter by melting the inner layer of the balloon or by using an adhesive (col. 4 lines 45-47) and Parker teaches that coextruded layers may be adhered to a substrate with or without an adhesive. The limitation of biaxially orienting both layers as set forth in claims 60 and 65 would have been obvious in view of the above noted teaching to form the balloon from a double layer tube and Levy's teaching to biaxially orient a tube. The limitation of

the relative melting points of the layers as set forth in claim 65 would have been obvious in view of Dyke's teaching to heat the inner layer (heat sealable bands) of the balloon to fuse the balloon to a catheter tube and Parker and Japan '353's teaching to make one layer of a tube out of a material which has a lower melting point than the material of another layer. The limitation of the material of the outer layer as set forth in claims 62-64 and 67-70 would have been obvious in view of Levy's al's teaching that the biaxially oriented material of the balloon may be a polymer such as polyethylene terephthalate. The limitation of the bonding material as set forth in claims 61, 62, 66 and 68 would have been obvious in view Dyke's teaching to make a sealable layer out of polyurethane, Parker's teaching to make a sealable layer out of polyethylene or Japan's teaching to make the heat sealable layer out of polyethylene.

8) Claims 71-79 are rejected under 35 U.S.C. § 103 as being unpatentable over Levy in view of Dyke, "Coextruded composite film" by Parker and Japan '353 (JA 53-45353) taken alone or further in view of Japan '463 (JA 58-188463) as applied above and further in view of Merrill and Lambert.

Levy does not specifically recite coating the outer layer with a hydrophilic lubricous plastic.

Merrill teaches coating a balloon catheter with a hydrophilic material such as N-pyrrolidone.

Lambert teaches coating a catheter with a hydrophilic material such as polyvinylpyrrolidone. Lambert teaches that the hydrophilic coating has a much lower coefficient of friction when wet. Lambert teaches providing the hydrophilic coating on polymeric substrates such as polyesters.

As to claim 71, it would have been obvious to coat the outer layer with a hydrophilic lubricous plastic so that advantageously the outer polymeric surface of the balloon catheter will have a low coefficient of friction when wet since (a) Levy teaches fabricating a catheter comprising the balloon and (b) Merrill and Lambert suggest coating a catheter with a hydrophilic plastic coating, which one of ordinary skill in the art would readily recognize becomes slippery when wet.

The limitation of claim 74 would have been obvious in view of Merrill's teaching to use N-vinyl pyrrolidone as a hydrophilic material. The limitations of claims 75-79 would have been obvious for the reasons given above with respect to claims 66-70. As to claim 72, note the examiner's comments given for the bonding step in claim 59. As to claim 73, note the examiner's comments given for claim 65.

9) REMARKS

Applicant's arguments with respect to claims 59-79 have been considered but are deemed to be moot in view of the new grounds

of rejection. Applicant's arguments filed 3-31-95 have been fully considered but they are not deemed to be persuasive.

Applicant argues that Wang et al "is not of good date". Page 9 of response filed 3-31-95. The examiner disagrees that Wang et al is not available as prior art against claims 59-79 under 102 (e) since the filing date of Wang et al is earlier than the earliest filing date which claims 59-71 are entitled to. See MPEP 201.11. It is noted that applicant fails to argue that each of claims 59-71 are fully supported by 07/411,649.

Trotta et al (filed 11-29-89), Lombardi et al (filed 1-14-91) and Radisch et al (filed 12-20-91) are cited of interest to show a balloon having plural layers.

10) No claim is allowed.

11) Any inquiry concerning this communication or earlier communications from the examiner should be directed to Steven D. Maki whose telephone number is (703) 308-2068. The examiner can normally be reached on Monday to Friday from 9:30 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Ball, can be reached on (703) 308-2058. The fax phone number for this Group is (703) 305-3601. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0651.

Steven D. Maki
June 21, 1995

6-21-95

STEVEN D. MAKI
PRIMARY EXAMINER
GROUP 1300